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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,166	08/31/2001	David R. Elmaleh	MGA-003.01	1584

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FOLEY HOAG, LLP  
PATENT GROUP, WORLD TRADE CENTER WEST  
155 SEAPORT BLVD  
BOSTON, MA 02110

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/945,166</b>	Applicant(s) <b>Elmaleh et al.</b>	
	Examiner <b>Jane Zara</b>	Art Unit <b>1635</b>	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p>			
<p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p>			
<p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p>			
<p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p>			
<p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p>			
<p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>			
<b>Status</b>			
<p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 8, 2003</u></p>			
<p>2a) <input type="checkbox"/> This action is FINAL.</p>		<p>2b) <input checked="" type="checkbox"/> This action is non-final.</p>	
<p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
<b>Disposition of Claims</b>			
<p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-24</u> is/are pending in the application.</p>			
<p>4a) Of the above, claim(s) <u>15-24</u> is/are withdrawn from consideration.</p>			
<p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p>			
<p>6) <input checked="" type="checkbox"/> Claim(s) <u>1-14</u> is/are rejected.</p>			
<p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p>			
<p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
<b>Application Papers</b>			
<p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p>			
<p>10) <input checked="" type="checkbox"/> The drawing(s) filed on <u>Aug 31, 2001</u> is/are a) <input checked="" type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.</p>			
<p>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p>			
<p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.</p>			
<p>If approved, corrected drawings are required in reply to this Office action.</p>			
<p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
<p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p>			
<p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p>			
<p>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</p>			
<p>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</p>			
<p>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p>			
<p>*See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>			
<p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p>			
<p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>			
<b>Attachment(s)</b>			
<p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p>		<p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p>	
<p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p>		<p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p>	
<p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>10</u></p>		<p>6) <input type="checkbox"/> Other: _____</p>	

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### **DETAILED ACTION**

This Office action is in response to the communications filed December 30, 2002 and April 8, 2003, Paper Nos. 12 and 15, respectively.

Claims 1-24 are pending in the instant application.

#### *Election/Restriction*

Applicant's election with traverse of Group I in Paper No.12 is acknowledged. The traversal is on the ground(s) that the search of one group would necessarily include a search of the remaining groups' claims, and would not constitute a serious burden on the examiner. This is not found persuasive because a search of the distinct and independent Group I would be overlapping but not necessarily coextensive with each of the searches required for proper examination of the other groups. The Groups furthermore require searches of different, albeit overlapping art, and also require consideration of different issues for different groups, including enablement issues.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 12.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7, 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4 and 11, line 4, the metes and bounds of the term "analog" cannot be determined. Appropriate clarification is requested.

In claims 5-7 and 12-14, it is unclear whether the various components (e.g. the targeting moiety, oligonucleotide and detectable label) listed in the corresponding claims are directly coupled to each other, or indirectly coupled to each other. Appropriate clarification is requested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothschild et al. Rothschild et al teach conjugates comprising an oligonucleotide that targets to a sequence of interest ( antisense sequences), a protein targeting moiety, a polypeptide therapeutic agent and a fluorescent or chemiluminescent detectable label, which targeting moiety localizes to a site in an organism, and wherein the targeting moiety, detectable label and nucleotide are optionally coupled covalently to each other (See especially the abstract; col. 1, line 23-col. 3, line 20; col. 4, lines 41-56; col. 7, lines 34-65; col. 9, line 40- col. 10, line 64; col 11, line 56-col. 13, line 46; col. 16, line 46-col. 17, line 42; col. 18, lines 22-39; col. 23, line 24-col. 24, line 62; col. 26, lines 22-39; col. 27, lines 49-62).

Claims 1-5, 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Papahadjopoulos et al.

Papahadjopoulos et al teach conjugated complexes comprising an oligonucleotide that targets a sequence of interest (an antisense), a protein targeting moiety that localizes to a site in an organism, and optionally further comprising a chemiluminescent detectable label, wherein the

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oligonucleotide and the targeting moiety are coupled (see especially col. 3, lines 25-34; col. 17, lines 14-58; col. 20, line 40-col. 21, line 37).

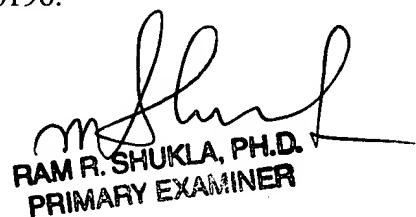
### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

August 8, 2003



RAM R. SHUKLA, PH.D.  
PRIMARY EXAMINER